Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Wayne R. Andersen	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	3 C 5861	DATE	12/23/2003
CASE TITLE	Genendo Pharmaceuticial et al vs. Tommy Thompson et al		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ Local Rule 41.1 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] **Enter MEMORANDUM, OPINION AND ORDER: For the foregoing reasons, we grant the motion [19-1] of the defendant, Tommy Thompson in his capacity as Secretary of the United States Department of Health and Human Services and Mark McClelland in his capacity as Commissioner of the Food and Drug Administration to dismiss Plaintiffs' complaint pursuant to FRCP 12(b)(1). This case is hereby terminated. This is a final and appealable order.**

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		number of notices	Document Number
	No notices required.		DEC 29 2003	
	Notices mailed by judge's staff.		date docketed	
	Notified counsel by telephone.			
✓	Docketing to mail notices.		docketing deputy initials	32
✓	Mail AO 450 form.	U.S. DISTRICT COURT CLERK 03 DEC 28 PM 8:27		
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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

GENENDO PHARMACEUTICAL N.V., a Netherlands Antilles company, and PHIL AND KATHY'S, INC., an Illinois corporation,	)	DOCKETED DEC 2 9 2003
Plaintiff,	)	**No. 03 C 5861**
v.	)	**Wayne R. Andersen District Judge**
TOMMY THOMPSON, in his official capacity of Secretary, United States Department of Health and Human Services, and MARK B. McCLELLAND, M.D., Ph.D., in his capacity as Commissioner of Food and Drugs,	)	
Defendants.	)	

MEMORANDUM, OPINION AND ORDER

This case is before the Court on the motion of the defendants, Tommy Thompson in his capacity as Secretary of the United States Department of Health and Human Services, and Mark McClelland in his capacity as Commissioner of the Food and Drug Administration ("Defendants") to dismiss plaintiffs' Genendo Pharmaceutical and Phil and Kathy's Inc. ("Plaintiffs") complaint pursuant to Fed.R.Civ.P. 12(b)(1) and 12(b)(6). For the following reasons, we grant the motion to dismiss.

BACKGROUND

Plaintiffs filed this action for declaratory and injunctive relief, asking this Court to declare that certain methods of importing drugs are legal and demanding the return of drug products that were seized pursuant to a criminal search warrant. Plaintiffs further seek to

enjoin the Food and Drug Administration ("FDA") from taking enforcement action against them.

Plaintiff Genendo purchases world wide prescription drugs directly from wholly-owned subsidiaries or authorized distributors of the manufacturer. Genendo imports some of the drugs it purchases to FDA-licensed re-packaging and re-labeling companies in the United States for sale inside or outside the United States. Plaintiff Phil and Kathy's, Inc. is the parent corporation of Alliance Wholesale Distributors and Local Repack, Inc. Local Repack is registered with the FDA as a drug re-packer/re-labeler. Local Repack re-packs and re-labels drugs to bring the packaging and labeling of the packages into compliance with the Act and applicable regulations.

On July 9, 2003, federal agents executed a criminal search warrant at the premises of Local Repack, in Richton Park, Illinois, and seized a quantity of prescription drugs. At that time, neither Plaintiff challenged the search warrant or sought return of the seized drugs pursuant to Fed.R.Crim.P. 41(g). Instead, on August 20, 2003, Plaintiffs filed this action for declaratory judgment and injunctive relief against the Defendants.

In a separate action, on September 15, 2003, the United States filed a complaint for forfeiture and initiated an in rem seizure of certain articles in the possession of Local Repack. The government's complaint alleges that the articles are in violation of the new drug, adulteration, and misbranding provision of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 355(a), 351(a)(2)(B), 352(c), and 352(f)(1). The government alleges that Local Repack failed to comply with the FDA's good manufacturing practice ("GMP") regulations, 21 C.F.R. Part 211, regarding the unlawful importation and repacking of foreign label drugs.

On September 19, 2003, Plaintiff Phil and Kathy's filed a Statement of Interest regarding the seized articles and, a week later, moved to dismiss the forfeiture complaint and quash the seizure warrant.

DISCUSSION

Federal Rule of Civil Procedure 12(b)(1) provides for dismissal of claims over which a federal court lacks subject matter jurisdiction. In assessing a motion to dismiss, the court accepts allegations in the complaint as true to the extent that they are uncontroverted by submitted affidavits. In reviewing a 12(b)(1) motion to dismiss, a court may look beyond the complaint and view any extraneous evidence submitted by the parties to determine whether subject matter jurisdiction exists. *United Transp. Union v. Gateway Western Ry. Co.*, 78 F.3d 1208, 1210 (7th Cir. 1996). The plaintiff bears the burden of establishing that the jurisdictional requirements have been met. *Kontos v. United States Dep't of Labor*, 826 F.2d 573, 576 (7th Cir. 1987).

I. Sovereign Immunity

Defendants first argue that Plaintiffs' Complaint is subject to dismissal because the Government did not waive sovereign immunity and, therefore, cannot be sued. We reject this argument because, in their brief, Plaintiffs claim that Defendants violated the Administrative Procedures Act ("APA"). The APA contains an explicit waiver of sovereign immunity. 5 U.S.C. § 704. Therefore, we deny the motion to dismiss on this basis.

II. Plaintiff's Claims Are Not Reviewable By This Court

A. Court Lacks Jurisdiction To Enjoin FDA Enforcement Action

In Count III of the Complaint, Plaintiffs seek an order "prohibiting the FDA from continuing to seize drugs which meet the importation method described in paragraphs 21 and 22 of this Count" as well as an order requiring the FDA to return the drugs that were seized pursuant to the July 9, 2003 criminal search warrant. Plaintiffs thus seek pre-enforcement review as to whether the FDA can proceed against Plaintiffs or the products they wish to import.

We find that granting the requested relief would not only impair and impede an ongoing criminal investigation but would also prevent the government from enforcing the FDCA against Plaintiffs' products in a civil seizure action pursuant to 21 U.S.C. § 334. This relief cannot be granted for the law is well-settled that the district courts lack jurisdiction to enjoin enforcement proceedings brought pursuant to the FDCA. *See Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950).

In *Ewing*, the Supreme Court held that district courts do not have jurisdiction to review the FDA's determination that there is probable cause to believe that a product violates the FDCA because Congress, in enacting the FDCA, did not intend to permit pre-enforcement judicial review:

> Judicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the [FDCA]. Congress made numerous administrative determinations under the Act reviewable by the courts. But it did not place the finding of probable cause under [21 U.S.C. § 334] in that category.

Id. at 600-01.

The Supreme Court pointed out that there would be ample opportunity for a claimant to litigate any constitutional, statutory, or factual claims in the seizure action itself, noting that "it has never been held that the hand of government must be stayed until the courts have an opportunity to determine whether the government is justified in instituting suit in the courts ... It is sufficient, where only property rights are concerned, that there is at some stage an opportunity for a hearing and a judicial determination." *Id.* at 598-99.

The policy behind the Supreme Court's view is that the speedy protection afforded the public by civil seizure actions would be impaired if district courts could intercede and enjoin FDA officials from initiating enforcement proceedings. *Id.* at 601. The *Ewing* decision has been "consistently and strictly observed" by the lower courts, which have interpreted the decision to "preclude[] judicial interference with the FDA's decision to institute enforcement actions, whatever the precise context." *United States v. Alcon Labs. v. United States*, 636 F.2d 876, 881-82 (1st Cir.), *cert. denied*, 451 U.S. 1017 (1981). *See also Premo Pharm. Labs. v. United States,* 629 F.2d 795, 801 (2d Cir. 1980) ("well-settled" that federal courts "lack jurisdiction to enjoin seizure actions instituted by the FDA"); *Southeastern Minerals v. Harris,* 622 F.2d 758, 763-64 & n. 10 (5th Cir. 1980).

Therefore, in accord with *Ewing* and its progeny, we find that we lack jurisdiction to make a determination that the FDA cannot initiate seizures or other enforcement actions under the FDCA against Plaintiffs or their products. Rather, as *Ewing* makes clear, the appropriate forum for reviewing the decision to bring a seizure action is in defense of the seizure itself.

B. Court Lacks Jurisdiction Over Plaintiffs' Declaratory Claims

As noted above, Plaintiffs seek a declaration from this Court that its proposed importation and re-packing scheme is permissible under the FDCA (Count I) and that the drugs seized pursuant to the criminal search warrant were not subject to seizure (Count II). Defendants argue that Plaintiffs' preemptive suit is improperly filed because there has been no final agency action regarding Plaintiffs' re-packing scheme, making Plaintiffs' action unripe.

The APA permits judicial review of "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. "Final agency action" is both a critical prerequisite to Article III justiciability, namely ripeness, and a necessary element of a cause of action under the APA. *See, e.g.*, 5 U.S.C. § 704; *Dalton v. Specter*, 511 U.S. 462, 469 (1994); *Abbs v. Sullivan*, 963 F.2d 918, 925-26 (7th Cir. 1992).

As the Supreme Court has explained, two conditions must be satisfied for agency action to be final: "First, the action must mark the 'consummation' of the agency's decisionmaking process–it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which 'rights or obligations have been determined' or from which 'legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (citations omitted). The Seventh Circuit has observed that ordinarily that "means a final order imposing some sort of sanction." *Abbs*, 963 F.2d at 926. A formally promulgated regulation of industry-wide application can likewise constitute final agency action. *See Abbott*, 387 U.S. at 151. However, nothing remotely comparable to any such events has occurred in this case to date, nor does Plaintiffs' Complaint purport to identify any action on the part of the FDA that would even arguably rise to the level of "final agency action" under the APA.

Instead, Plaintiffs' Complaint refers only to unspecified statements assertedly made by government attorneys and investigators, which Plaintiffs ascribe as the FDA's "position." Thus, in Count I, Plaintiffs describe the importation scheme it proposes to carry out and alleges that it "proposed this to the FDA through the United States Attorneys office in the Northern District of Illinois and through Special Agent Lawrence E. Dennelly of the FDA, Office of Criminal Investigation." Based on nothing more than these alleged discussions with federal prosecutors and an FDA agent, Count I of Plaintiffs' Complaint repeatedly refers to the FDA's supposed "position" or "stance" and asserts that the FDA has thereby "created an uncodified, unreasonable, and unpromulgated rule." Count II describes the July 9, 2003 execution of a search warrant at the premises of Local Repack which resulted in the seizure of the drugs. The Complaint then alleges that the FDA has "refused to release and return" the drugs despite negotiations between the parties.

We find that Genendo's allegations of negotiations and discussions with various federal agents and attorneys are insufficient to demonstrate final agency action on the part of the FDA. We cannot characterize the "positions" that Plaintiffs ascribe to the FDA as final agency action. Rather than describing the consummation of the agency's decisionmaking process as one by which rights have been determined and legal consequences will flow, Plaintiffs' Complaint describes, at most, the statements of subordinate agency officials in the course of conducting routine, preliminary investigative activity. It is well-settled, however, that an agency's investigatory activity does not constitute final agency action. *See, e.g., Reliable Automatic Sprinkler Co., Inc. v. CPSC,* 324 F.3d 726, 731-32 (D.C. Cir. 2003) (actions which are merely investigatory are not final agency action); *Abbs*, 963 F.2d at 926-27

(no final agency action when investigation has not even reached administrative complaint stage).

Statements of lower-level agency officials likewise do not rise to the level of final agency action–even when they are contained in warning letters or other official regulatory correspondence. *See, e.g., Western Ill. Home Health Care v. Herman,* 150 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan*, 791 F. Supp. 1499, 1503-04 (D. Kan 1992).

Therefore, whatever negotiations or discussions Plaintiffs and their attorneys may have had with the government in the context of the ongoing criminal investigation and the execution of the July 9, 2003 search warrant, such activities do not amount to the creation of an "unpromulgated rule" as Plaintiffs suggest. Likewise, the allegations fall short of anything approaching final agency action sufficient to support a cause of action under the APA or otherwise invoke the jurisdiction of this Court.

Finally, the government's recent institution of a civil *in rem* seizure does not alter this conclusion. In a case very similar to the instant case, *Clinical Reference Laboratory, Inc. v. Sullivan*, 791 F. Supp. 1499 (D. Kan. 1992), the government brought a seizure action against certain of the plaintiff CRL's products two months after CRL had filed an action for declaratory and injunctive relief against the FDA. Despite the initiation of seizure proceedings, the court concluded that final agency action had not occurred and dismissed CRL's claims as unripe:

> CRL also contends that the subsequent seizure action instituted by the FDA amounts to final agency action. The court disagrees. Such actions are not final agency determinations that the articles seized violate provisions of the FDCA; they are merely determinations that there is reason to aver that a violation has occurred. The judicial investigation and resolution initiated by a seizure action, together with an ongoing administrative investigation by the FDA, are only part of the process through which the FDA reaches a final determination regarding the challenged articles. Such seizures, especially when based upon agency positions that are themselves not final, do not constitute final action.

Id. at 1504.

Thus, just as the issuance of an administrative complaint merely commences an administrative proceeding by which legal rights and obligations will be defined and does not constitute final agency action, so too does the institution of a civil seizure action simply initiate a process whereby the legal status of the products at issue will be determined. Unlike a promulgated regulation or an administrative order, the FDA's filing of a forfeiture complaint does not consummate the agency's decision-making process or definitively determine the status of the products seized, but merely indicates that the agency has reason to believe a violation has occurred.

Moreover, the seizure action itself provides a forum within which Plaintiffs can litigate the very issues it seeks preemptively to raise here. Simply put, parties may not "file preemptive suits for declaratory or injunctive relief in order to avoid what they perceive as unfavorable agency positions before the agency has had an opportunity to reach a final determination on the merits of the issue." *Clinical Reference Laboratory*, 791 F. Supp. at 1504. *See also Reliable,* 324 F.3d at 732 (if government brings enforcement proceeding, parties may defend on ground that agency lacks jurisdiction but may not preemptively challenge jurisdiction before government has taken action to enforce law against them).

Finally, Plaintiffs have failed to avail themselves of several different avenues through which they can obtain judicial review of their claims with respect to their proposed importation and re-packing scheme and also the return of the drugs seized. First, Plaintiffs could have sought a formal administrative ruling from the FDA on the legality of its proposed importation by filing either a citizen petition or a request for an advisory opinion with the agency. See 21 C.F.R. §§ 10.25, 10.30, 10.85. The agency's response to such a petition or request constitutes inal agency action and is subject to immediate judicial review. 21 C..F.R. § 10.45(d). Second, as noted above, Plaintiffs can litigate the legality of their conduct in the seizure action recently filed by the government.

For all of these reasons, we find that Plaintiffs' claims for declaratory and injuntive relief are not ripe, and we grant Defendant's motion to dismiss for lack of subject matter jurisdiction.

CONCLUSION

For the foregoing reasons, we grant the motion of the defendants, Tommy Thompson in his capacity as Secretary of the United States Department of Health and Human Services and Mark McClelland in his capacity as Commissioner of the Food and Drug Administration to dismiss Plaintiffs' Complaint pursuant to Fed.R.Civ.P. 12(b)(1). This case is hereby terminated. This is a final and appealable order.

It is so ordered.

Wayne R. Andersen
United States District Judge

Dated: December 23, 2003